IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA AB, Plaintiff/Counterclaim Defendant, v. APOTEX INC., and APOTEX CORP., Defendants/Counterclaim Plaintiffs.	C.A. No. 24-551-RGA

PLAINTIFF'S OPENING BRIEF IN SUPPORT OF ITS MOTION TO DISMISS DEFENDANTS' COUNTERCLAIMS PURSUANT TO FED. R. CIV. P. 12(b)(6)

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

I. INTRODUCTION

Pursuant to Fed. R. Civ. P. 12(b)(6), Plaintiff/Counterclaim Defendant AstraZeneca AB ("AstraZeneca" or "Plaintiff") seeks to dismiss Defendants Apotex Inc. and Apotex Corp.'s ("Apotex" or "Defendants") counterclaims for failure to state a claim for relief.

Contrary to the standards applicable to Fed. R. Civ. P. 8(a), where "there must be sufficient factual matter to state a facially plausible claim to relief," *Allergan Holdings Unlimited Co. v. MSN Labs. Private Ltd.*, 2024 WL 3444368, at *2 (D. Del. July 17, 2024) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009), Defendants' declaratory judgment counterclaims are entirely conclusory and further fail to establish a case or controversy. None of the counterclaims, Counts I, III, V, and VII for non-infringement and Counts II, IV, VI, and VIII for invalidity, include any factual support. Further, any attempt by Apotex to merely rely on its March 22, 2024 "Notice Letter" to substitute for missing facts (D.I. 11, Counterclaims ¶ 18) fails under controlling law.[1] *See Senju Pharm. Co., Ltd. v. Apotex, Inc.*, 921 F. Supp. 2d 297, 302-03 (D. Del. 2013) (dismissing counterclaims despite defendant's argument that ANDA notice letters provided "abundant detail" about bases for counterclaim contentions). Moreover, Apotex's declaratory judgment counts of non-infringement, wherein it asserts that none of the acts of direct infringement addressed in 35 U.S.C. § 271(a) would apply to its potential future product (*see, e.g.*, D.I. 11, Counterclaims ¶ 24 ("Apotex has not, does not, and *will not* infringe…*directly* or indirectly…any valid, enforceable, and properly

[1] The Notice Letter also does not contain detailed non-infringement positions for any of U.S. Patent Nos. 7,919,598 ("the '598 patent"), 8,501,698 ("the '698 patent"), 8,685,934 ("the '934 patent"), and 9,616,028 ("the '028 patent) (collectively, the "Patents-in-Suit"), does not contain any invalidity positions under 35 U.S.C. § 112 for any of the Patens-in-Suit, and does not contain any invalidity positions under 35 U.S.C. §§ 102 or 103 for the '598 and '698 patents. Thus, even if Apotex's proposed reliance on its Notice Letter were legally permissible—it is not—the Notice Letter still fails to provide sufficient facts to state a plausible claim for relief for at least Counts I-V and VII.

construed claim of the '598 patent.") (emphases added)), cannot be maintained as Apotex already enjoys protection under the safe harbor of 35 U.S.C. § 271(e)(1) for a charge of direct infringement.

Accordingly, AstraZeneca respectfully submits that Defendants' counterclaims should be dismissed pursuant to Rule 12(b)(6).

II. PROCEDURAL AND FACTUAL BACKGROUND

The present action arose from Apotex's March 22, 2024, "Notice Letter," which stated that Apotex had submitted to the FDA an Abbreviated New Drug Application ("ANDA") with a "Paragraph IV" certification seeking approval to market a generic copy of AstraZeneca's XIGDUO® XR (dapagliflozin and metformin HCl extended-release) product prior to the expiration of AstraZeneca's Orange Book-listed Patents-in-Suit. The filing of an ANDA is a statutory act of infringement under 35 U.S.C. § 271(e)(2). *IGI Labs., Inc. v. Mallinckrodt LLC*, No. 13-2044-RGA, 2014 WL 1652790 at *1 (D. Del. Apr. 22, 2014) (citing 35 U.S.C. § 271(e)(2)(A)). In this case, pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) and within forty-five days from the date AstraZeneca received the Notice Letter, AstraZeneca filed a complaint against Apotex on May 6, 2024 for infringement of the Patents-in-Suit under 35 U.S.C. § 271(e)(2). (D.I. 1.)

Apotex answered and counterclaimed on September 3, 2024, seeking a declaratory judgment of non-infringement and invalidity of the Patents-in-Suit. (D.I. 11, Counterclaims ¶¶ 1-77.) Apotex's counterclaims, however, are entirely barebones and conclusory. The non-infringement counterclaims, Counts I, III, V, and VII assert without any factual support that "[t]he manufacture, use, sale, offer for sale within, and/or importation" of Apotex's ANDA products does not and will not constitute infringement. (*Id.* at Counterclaims ¶¶ 25, 39, 53, and 67.) Similarly, Apotex's invalidity counterclaims, Counts II, IV, VI, and VIII merely recite conclusory statements regarding, "conditions of patentability specified in Title 35 of the United States Code," such as §§

102, 103, and 112, and certain purported elements of those grounds. (*Id.* at Counterclaims ¶¶ 29-32, 43-46, 57-60, and 71-74.) Apotex fails to include any supporting facts, such as alleged prior art, and at most generically relies on "the reasons set forth in the…Notice Letter," (*Id.*) which, as stated above (*supra*, note 1), is legally impermissible and also factually insufficient.

III. ARGUMENT

Apotex's counterclaims provide no more than formulaic recitations of the infringement statute or conditions of patentability. There is no comparison of the claims to the allegedly noninfringing product, no specific prior art is identified, and no specific defects with the patent's disclosure or claims are asserted. These counterclaims thus fail to meet the standards of Fed. R. Civ. P. 8(a), as required by the U.S. Supreme Court in *Bell Atl. Corp. v. Twombly* and *Iqbal*. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 569 (2007) (holding that pleadings must contain "enough facts to state a claim to relief that is plausible on its face"); *Iqbal*, 556 U.S. at 678 ("To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'") (quoting *Twombly*, 550 U.S. at 569); *see also Senju Pharm. Co. v. Apotex, Inc.*, 921 F. Supp. 2d 297, 303 (D. Del. 2013) ("[T]he court concludes that the pleading standards set forth in *Twombly* and *Iqbal* apply to counterclaims of invalidity."); *Petra Mezzanine Fund, L.P. v. Willis*, No. 12-601, 2012 WL 5382944, at *1-2 (D. Del. Nov. 1, 2012) (applying *Twombly* in considering a Rule 12(b)(6) motion to dismiss counterclaims); *Allergan*, 2024 WL 3444368, at *2 (applying *Iqbal* and *Twombly* in granting a Rule 12(b)(6) motion to dismiss counterclaim).

Dismissal under Fed. R. Civ. P. 12(b)(6) is warranted because, lacking any factual support, Apotex has failed to provide "fair notice of what the claim is and the grounds upon which it rests." *Twombly*, 550 U.S. at 555. Dismissal is also warranted because Apotex further fails to establish a

declaratory judgment case or controversy for its non-infringement counterclaim under 35 U.S.C. § 271(a), which is prohibited under the safe harbor provisions of 35 U.S.C. § 271(e)(1).

A. Apotex's Conclusory Non-Infringement Counterclaims I, III, V, and VII Fail to State a Claim of Non-Infringement Upon Which Relief May Be Granted and Does Not Establish a Declaratory Judgment Case or Controversy

The operative contention in Counts I, III, V, and VII of Apotex's counterclaims is its assertion that "[t]he manufacture, use, sale, or offer for sale within, and/or importation into the United States of Apotex's ANDA Products does not and will not constitute infringement (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), of any valid, enforceable, and properly construed claim of the [Patents-in-Suit]." (D.I. 11, Counterclaims ¶¶ 25, 39, 53, and 67.) While Apotex seems to have simply copied the statutory language for direct infringement from 35 U.S.C. § 271(a), no purported reasons, rationale, or factual support is even alleged. Indeed, Apotex does not address a single specific claim or any element thereof in its conclusory assertion. These "naked assertions devoid of further factual enhancement" are plainly insufficient to state a claim. *Iqbal*, 556 U.S. at 678 (citation omitted).

As other courts have held, it is not sufficient under *Twombly* and *Iqbal* for a noninfringement counterclaim to merely allege that each element of a patent claim was not infringed—a level of detail Apotex did not even provide here—without alleging the factual basis for the contention. For example, at a hearing granting a Rule 12(b)(6) motion to dismiss counterclaims of noninfringement and invalidity in *AstraZeneca LP et al. v. Sandoz Inc.*, C.A. No. 15-1012-RGA, D.I. 37 at 52-53 (D. Del. April 5, 2016) (Exhibit A), this Court stated the following:

> THE COURT: I think that declaratory judgment of noninfringement ought to say at least that here's an element, a claim limitation that Sandoz's product, that plaintiff cannot prove Sandoz's product meets because it doesn't have X or, you know, something along those lines. I'm not talking about a long song and dance here, but

> I'm talking about something that I could see and say, yes, okay, that's plausible. . . .

With nearly identical language to Apotex's noninfringement counterclaims here, Sandoz's noninfringement counterclaim in that case conclusorily stated "[t]he manufacture, use, offer for sale, sale, importation, and/or marketing of the ticagrelor tablet 90 mg product described in Sandoz's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '934 patent, either literally or under the doctrine of equivalents." *AstraZeneca LP et al. v. Sandoz Inc.*, C.A. No. 15-1012-RGA, D.I. 11, Counterclaims ¶ 20 (D. Del. Dec. 30, 2015) (Exhibit B). As another example, in *Deerpoint Grp., Inc. v. Acqua Concepts, Inc.*, the court dismissed defendant's counterclaims under Rule 12(b)(6) even though they "set[] forth sixteen reasons to invalidate the patent or find that there was no infringement" but which "only set[] forth conclusory statements with no supporting factual allegations that are []sufficient to state a plausible claim for relief." No. 14-1503-SAB, 2014 WL 7178210, at *3, 4 (E.D. Cal. Dec. 16, 2014) (citing *Iqbal*, 556 U.S. at 678). Similarly, the court in *Macronix Int'l Co., Ltd. v. Spansion, Inc.* applied *Twombly* and *Iqbal* to dismiss infringement claims that only "allege[] that each element of a cited claim is infringed and then parroted the claim language for each element" but "d[id] not allege how the offending products [meet the limitations of] the [asserted] claims recited" as "required to put [the accused] on notice of what it has to defend and to make a plausible showing of infringement." 4 F. Supp. 3d 797, 804 (E.D. Va. 2014).

In this case, Apotex did not include any alleged facts in its counterclaims Counts I, III, V, or VII to plausibly allege why or how there is allegedly no infringement. Apotex thus failed to plead with sufficient specificity to provide AstraZeneca "fair notice of what the claim is and the grounds upon which it rests." *Twombly*, 550 U.S. at 555. Accordingly, Apotex's non-infringement

counterclaims should be dismissed at least for their lack of sufficient allegedly factual matter to "state a claim to relief that is plausible on its face." *Iqbal*, 556 U.S. at 678.

Moreover, although Apotex parrots the language of 35 U.S.C. § 271(a), (*See* D.I. 11, Counterclaims ¶¶ 25, 39, 53, and 67), and states "Apotex has not, does not, and *will not* infringe…*directly* or indirectly…any valid, enforceable, and properly construed claim of the [Patents-in-Suit]," (D.I. 11, Counterclaims ¶¶ 24, 40, 54, and 68), it cannot state a claim for declaratory judgment of no direct infringement under 35 U.S.C. § 271(a). Specifically, because the "safe harbor" provisions of 35 U.S.C. § 271(e)(1) protect Apotex from a charge of direct infringement based on its ANDA filing, it cannot establish a case or controversy under § 271(a). *See Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274, 1279 (Fed. Cir. 2014) (no declaratory judgment case or controversy where the accused product is protected under 35 U.S.C. § 271(e)(1) from charges of infringement); *Telectronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1523 (Fed. Cir. 1992) ("The language of § 271(a) clearly specifies only the making, using or selling of a patented invention as infringing activities. Under § 271(e)(1), these potentially infringing activities are exempt if performed solely for uses reasonably related to the development of information for FDA approval.").

As explained by the Federal Circuit, "[t]o permit [the defendant] to be protected from direct suit for infringement [under § 271(e)(1)] and yet allow the same activities to be subject to suit in a declaratory judgment action would be nonsensical." *Intermedics, Inc. v. Ventritex Co.*, 991 F.2d 808, at *4 (Fed. Cir. 1993) (unpublished); *see also Eisai Co. v. Mut. Pharm. Co.*, No. CIV.A. 06-3613(HAA), 2007 WL 4556958, at *17 (D.N.J. Dec. 20, 2007) ("[A]ctivities protected by the safe harbor provision cannot serve as the basis for a declaratory judgment of actual future infringement."). Notably, consistent with this precedent, AstraZeneca, in its Complaint (D.I. 1),

has only presently asserted infringement under 35 U.S.C. § 271(e)(2) based on the statutory act of Apotex's ANDA filing. *See IGI Labs.*, 2014 WL 1652790 at *1 (citing 35 U.S.C. § 271(e)(2)(A)). AstraZeneca has not asserted direct infringement under § 271(a).

Accordingly, AstraZeneca respectfully submits that Apotex's counterclaims Counts I, III, V, and VII should be dismissed for failure to state a claim as their conclusory averments lack plausible support for the alleged non-infringement and for failure to establish a case or controversy for declaratory relief.

B. Apotex's Conclusory Invalidity Counterclaims II, IV, VI and VIII Fail to State a Claim of Invalidity Upon Which Relief May Be Granted

Apotex's counterclaims Counts II, IV, VI, and VIII, rather than specifying any facts, broadly state that all claims are invalid "for failure to meet one or more of the conditions for patentability specified in Title 35 of the United States Code." (D.I. 11, Counterclaims ¶¶ 29, 43, 57, 71.) The counterclaims then generically recite legal elements of validity under 35 U.S.C. §§ 102 and 103, such as motivation to combine, anticipation and obviousness over the prior art, and then conclusorily assert that the Patents-in-Suit failed to meet the legal elements. (*Id.* at Counterclaims ¶¶ 30-31, 44-45, 58-59, 72-73.) The counterclaims then generically state that the claims are "further invalid for failure to satisfy the requirements of 35 U.S.C. § 112." (*Id.* at Counterclaims ¶¶ 32, 46, 60, 74). There are no supporting facts, no details, and nothing that would "provide [Plaintiffs] with adequate notice to frame an answer." *Abbott Diabetes Care, Inc. v. Dexcom, Inc.*, No. 05-590-GMS, 2006 WL 2375035, at *4 (D. Del. Aug. 16, 2006) (citing *Colburn v. Upper Darby Twp.*, 838 F.2d 663, 666 (3d Cir. 1988)).

These Counts are plainly insufficient to state a claim for relief because the factual allegations "must provide more than labels, conclusions, or a 'formulaic recitation' of the claim elements." *Allergan*, 2024 WL 3444368, at *2; *see also Iqbal*, 556 U.S. at 678. Indeed, this District

has dismissed a nearly identically-worded counterclaim for failure to meet the pleading standards of *Twombly* and *Iqbal*. *Senju Pharm.*, 921 F. Supp. 2d at 300, 303 (dismissing under Rule 12(b)(6) declaratory judgment counterclaims asserting that the patents-at-issue "are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to Sections 101, 102, 103 and/or 112").

More specifically, while Counts II, IV, VI, and VIII expressly rely on 35 U.S.C. §§ 102, 103, which respectively govern anticipation and obviousness, they fail to identify with specificity any prior art which would render any claim of the Patents-in-Suit unpatentable. (*See* D.I. 11, Counterclaims ¶¶ 30-31, 44-45, 58-59, 72-73.) As other courts have found under similar facts, this does not state a claim for relief. *See Crye Precision LLC v. Duro Textiles, LLC*, No. 15-cv-1681, 2015 WL 3751658, *9-10 (S.D.N.Y. June 16, 2015) (dismissing the defendant's declaratory judgment counterclaim of patent invalidity that, among other defects, "d[id] not identify any prior art that anticipates or renders obvious [plaintiff's] Patents"). Apotex's Counts II, IV, VI, and VIII provide no more than formulaic recitations of certain elements of 35 U.S.C §§ 102 and 103. For instance, without identifying any alleged prior art, Apotex asserts that:

> The claims of the '598 patent are invalid at least under 35 U.S.C. §§ 102 and/or 103 in view of the prior art. The differences between the subject matter claimed in the '598 patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious, at the time that the alleged inventions were made, to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

(*See* D.I. 11, Counterclaim ¶ 31.) The averments regarding invalidity under 35 U.S.C. § 112 are equally obtuse and unhelpful in providing any actual notice as they merely state that the claims are "further invalid for failure to satisfy the requirements of 35 U.S.C. § 112." (*Id.* at Counterclaims ¶¶ 32, 46, 60, 74).

Apotex's formulaic recitations are not "factual content that allows the court to draw the reasonable inference that [Plaintiffs are] liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 556). To the contrary, under similar facts, courts have routinely found that merely reciting generic patentability conditions failed to meet the *Twombly/Iqbal* pleading standard. For example, in *AstraZeneca LP et al. v. Sandoz Inc.*, C.A. No. 1:15-cv-01012-RGA, D.I. 37 at 52-53 (D. Del. April 5, 2016) (Exhibit A), this Court stated:

> THE COURT: And I think on the invalidity. . . . I think that you need to do something more than just say, they're obvious and valid for all the reasons, for all the prior art cited on the face of the patent, which in some ways is a very dubious way to actually raise the issue since not only do you have the presumption of validity, but you have the fact that those are things that we know were actually considered by the Patent Office. . . . So it's harder for me to say exactly what I think you should have here, but I think this is entirely bare bones and insufficient. So I'm not looking for a lot, but I'm looking for something more than you have.

As another example, in *Protomet Corp. v. Mastercraft Boat Co., LLC*, the court dismissed a count for declaratory judgment of invalidity that generically recited that "'any differences between subject matter claimed in the [patent] and prior art devices, such as... well-known spring-biased clamping devices, would have been obvious....'" without "actually say[ing] what prior art devices it is referring to or which 'well-known spring biased [clamping] devices' render the [patent] claim obvious." No. 3:13-CV-532-PLR-CCS, 2014 WL 5325360, at *1 (E.D. Tenn. Oct. 20, 2014). Just like Apotex's invalidity counterclaims, the invalidity counterclaim in *Protomet* "does not meet the *Twombly* and *Iqbal* standard because it contains no factual content much less enough for the Court to reasonably draw the inference that the [Plaintiffs]' patent is invalid." *Id.*

Accordingly, AstraZeneca respectfully submits that Apotex's counterclaims Counts II, IV, VI, and VIII should be dismissed for failure to state a claim, as their conclusory averments lack plausible support for the alleged invalidity of the Patents-in-Suit.

IV. CONCLUSION

For the reasons set forth above, Plaintiff respectfully requests that this Court dismiss Apotex's counterclaims pursuant to Fed. R. Civ. P. 12(b)(6) for failure to state a claim.

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